

JUN - 6 2003

K030964

Section 3
Calibration Plasma LMW Heparin - 510(k) Summary
(Summary of Safety and Effectiveness)

Submitted by:

Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, MA 02421
Phone: 781-861-4467
Fax: 781-861-4207

Contact Person:

Carol Marble, Regulatory Affairs Director
Phone: 781-861-4467 / Fax: 781-861-4207

Summary Prepared:

March 26, 2003

Name of the devices:

Calibration Plasma LMW Heparin

Classification names:

Common Name	Primary Calibrator
Product Code	JIS
Regulation Number	862.1150
Classification	Class II

Identification of predicate devices:

K002400 Assess Calibration Plasma

NOTE: This calibration plasma 510(k) cleared as part of analyzer systems, most recently the ACL Advance.

Description of the device/intended uses:

Calibration Plasma LMW Heparin is an *in vitro* diagnostic product intended as a tri-level calibrator to prepare calibration curves for use in chromogenic heparin assays.

Statement of Technological Characteristics of the Device Compared to Predicate Devices:

The new Calibration Plasma LMW Heparin is substantially equivalent in intended use and performance with heparin assays to the predicate calibrator: Assess Calibration Plasma.

Summary of Performance Data:

A precision study was performed with Calibration Plasma LMW Heparin (tri-level) over multiple days with multiple runs (n=60) using specific lots of IL reagents on IL instrumentation:

Description	Mean IU/mL	Within Run %CV	Between Run %CV	Total %CV
Level 1	-0.03	0.018 (SD)	0.008 (SD)	0.024 (SD)
Level 2	0.47	2.99	1.47	4.24
Level 3	0.80	2.21	0.00	2.58



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN - 6 2003

Ms. Carol Marble
Regulatory Affairs Manager
Instrumentation Laboratory Company
101 Hartwell Avenue
Lexington, Massachusetts 02421-3125

Re: k030964
Trade/Device Name: Calibration Plasma LMW Heparin
Regulation Number: 21 CFR § 862.1150
Regulation Name: Calibrator
Regulatory Class: II
Product Code: JIS, KFF
Dated: May 19, 2003
Received: May 30, 2003

Dear Ms. Marble:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

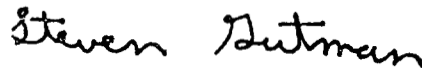
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K030964

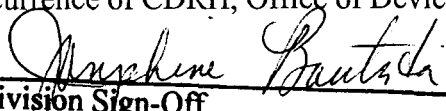
Device Name: Calibration Plasma LMW Heparin

Indications for Use:

Calibration Plasma LMW Heparin is an *in vitro* diagnostic product intended as a tri-level calibrator to prepare calibration curves for use in chromogenic heparin assays.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K030964

Prescription Use ☒
(Per 21 CFR 801.019)

OR Over-The-Counter Use ☐